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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,975	09/18/2003	Ingo Tamm	BURNHAM.005A	5524

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,975	TAMM ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10 and 35-57* is/are pending in the application.

4a) Of the above claim(s) *9,10,35-39,41-46 and 49-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40, 47, and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed August 10, 2006 and Supplemental Amendment filed August 22, 2006 are acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Group Art Unit 1648.

Election/Restriction

Newly submitted claims 35-57 and the new embodiments of claims 9 and 10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted claims are drawn to three different inventions:

I. Claims 9-46, drawn to an isolated compound that inhibits interaction of Survivin with hepatitis B X-interacting protein (HBXIP), wherein said compound comprises antisense nucleic acids or siRNA, classified in class 536, subclass 23.1.

II. Claims 40, 47, and 48, drawn to drawn to an isolated compound that inhibits anti-apoptotic activity of Survivin wherein said compound comprises a polyclonal antibody, classified in class 530, subclass 389.1.

III. Claims 49-57, drawn to a method of inhibiting Survivin, classified in class 435, subclass 344.1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The invention of the above group II has been examined in the action on the merits of February 22, 2006, and therefore claims 40, 47, and 48, directed to the invention of group II are presently examined. Accordingly, claims 9, 10, 35-39, 41-46, and 49-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Title

The new Title submitted by Applicant is acknowledged.

Claim Rejections - 35 USC § 101

The rejection of claim 9 under 35 U.S.C. 101 **is withdrawn** in view of Applicant's amendments to the claim.

Claim Rejections - 35 USC § 112

The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention **is moot** because claims 9 and 10 are withdrawn.

The rejection of claims 9 and 10 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement **is moot** because claims 9 and 10 are withdrawn.

The rejection of claims 9 and 10under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement **is moot** because claims 9 and 10 are withdrawn.

Claim Rejections - 35 USC § 102

Rejection of claims 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Banks et al. **is moot** because claims 9 and 10 are withdrawn.

Rejection of claims 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Yagihashi et al. **is moot** because claims 9 and 10 are withdrawn.

New Rejection

Claim Rejections - 35 USC § 112

Claims 40, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to an isolated compound that inhibits anti-apoptotic activity of Survivin by reducing the activity of hepatitis B-X-interacting protein. The claims encompass any isolated compound that inhibits anti-apoptotic activity of Survivin. The current specification contemplates compounds that may be useful to inhibit anti-apoptotic activity of Survivin such as: antisense nucleic acids, siRNA, antibodies, small molecules, peptides, and peptidomimetics (page 19, 20, 23, 24 and 25).

> (page 19, paragraph [51]) "Antisense nucleic acids, catalytic RNAs and siRNAs comprising a nucleotide sequences identical to a portion of the Survivin and/or HBXIP genes are contemplated in some embodiments of the present invention. However, nucleic acid sequences with insertions, deletions, and single point mutations relative to the target sequence are also effective for inhibition of gene expression."

> (page 23, paragraph [64]) "The activation of pro-Caspase-9 is measured in the presence of Survivin, HBXIP and the candidate chemical compound. This activation is compared with the activation of pro-Caspase-9 that is measured in the presence Survivin and HBXIP without the candidate chemical compound. If the candidate compound inhibits the interaction between Survivin and HBXIP, the amount of activation of pro-Caspase-9 will increase compared to the amount pro-Caspase-9 activation in the presence of Survivin and HBXIP without candidate compound. The characteristics of each library compound are encoded so that compounds demonstrating activity that prevents or otherwise disrupts the interaction between Survivin and HBXIP can be analyzed and features common to the various compounds identified can be isolated and combined into future iterations of libraries."

It is apparent that at the time when the current application was filed the Applicant did not have the possession of the claimed compounds that inhibit anti-apoptotic activity of Survivin.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification contemplates production of various compounds that would be effective in inhibiting the anti-apoptotic activity of Survivin. One of skill in the art would not know what are the structures of the claimed compounds, either the compounds are antisense nucleic acids, siRNA, antibodies, small molecules, peptides, or peptidomimetics. Applicant's claims pertain to a function of a compound that has an unknown structure. The claimed compounds have not been sufficiently described in terms of their structure and function. Claiming a product based on function (inhibiting the anti-apoptotic activity of Survivin) does not provide sufficient description of the product as claimed.

It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities. Therefore, structurally unrelated "molecules" encompassed by the claimed invention would be expected to have greater differences in their structural and functional characteristics and attributes. Mere idea or function is insufficient for written description.

> "a mere wish or plan" for obtaining an invention is not enough to comply with § 112, ¶ 1(*Regents of the University of California v. Eli Lilly & Co., 119* F.3d 559, at 1566).

> The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

The mere contemplation of the claimed genus in the specification is not sufficient to support the presently claimed invention directed to a genus of compounds that inhibit the anti-apoptotic activity of Survivin. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which are not conventional in the art as of applicant's effective filing date. Claiming a genus of compounds that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997).

Possession may be shown by actual reduction to practice (provided in the specification and/or the 37 U.S.C. 1.132 declaration), clear description of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics. Inc.*, 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claim Rejections - 35 USC § 102

Claims 40 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Banks et al. "Survivin does not inhibit caspase –3 activity" Blood, 2000).

Claims are drawn to an isolated compound that inhibits anti-apoptotic activity of Survivin, wherein the compound is an antibody. Banks disclose ban antibody binding Survivin (see page 4002, left column). It is noted that the antibody by binding Surviving prevents Survivin from binding to any protein including HBXIP. By this disclosure Banks anticipates the current claims.

Claims 40, 47, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Yagihashi et al. ("Detection of Anti-Survivin Antibody in gastrointestinal cancer patients" Clin Chem, 2001).

Claims are drawn to an isolated compound that inhibits anti-apoptotic activity of Survivin, wherein the compound is a polyclonal antibody. Yagihashi disclose a polyclonal antibody found in human sera binding to Survivin (see page 1730, left column). It is noted that the antibody by binding Surviving prevents Survivin from binding to any protein including HBXIP. By this disclosure Yagihashi anticipates the current claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner
10/20/06

Stacy B. Chen 10/20/06
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PRIMARY EXAMINER